Urgent Field Safety Notice

EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology.

April 2018

Medtronic reference: FA811

Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific production lots of its Covidien EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology.

Issue Description:

This recall is being conducted due to the potential for improper welding of the yellow staple guide to the instrument. Use of a device with an improperly welded staple guide may result in improper staple formation potentially leading to bleeding or anastomotic leak. This issue was identified during in-process Quality testing at the manufacturing facility. There have been no reports of serious injury related to this issue.

This recall affects only the item codes and lots listed below.

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Item Description</th>
<th>Affected Lots</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEM3335</td>
<td>EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology 3.5MM</td>
<td>N7J1145MX N7L0380MX N7L0762MX N7L1077MX N7M0733MX N7K0092MX N7L0457MX N7L0868MX N7M0144MX N7M0835MX N7K0692MX N7L0594MX N7L0940MX N7M0185MX N8A0144MX N7K0693MX N7L0676MX N7L1076MX N7M0732MX N8A0166MX</td>
</tr>
<tr>
<td>HEM3348</td>
<td>EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology 4.8MM</td>
<td>N7K0694MX N7L1078MX N7M0837MX</td>
</tr>
</tbody>
</table>

Medtronic requests that you quarantine and return any unused products of the item codes and lots detailed above. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below. If you have distributed Covidien EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology listed above, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes and lots must be returned.
Required Actions:
1. Please quarantine and discontinue use of the affected item code and lots listed on page one.
2. Please return affected product as indicated in Appendix A.
3. Complete the Return Verification Form **even if you do not have inventory**.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

We request that you contact Medtronic if you experienced quality problems or adverse events.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative at 00966114048888.

Sincerely,

Medtronic Saudi Arabia LLC

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Appendix A: Return Instructions:

<table>
<thead>
<tr>
<th>Customer with inventory</th>
<th>Customer with zero inventory</th>
<th>Where to send the completed form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchased directly from Medtronic</td>
<td>Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.</td>
<td>Complete form and check the box indicating “no inventory”</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Purchased from a distributor</td>
<td>Complete all fields on the form and contact your distributor directly to arrange for return of product</td>
<td>Complete form and check the box indicating “no inventory”</td>
</tr>
</tbody>
</table>

Appendix B

**Item code**

**Lot number**